

510(k) Summary

510(k) Submission Information:

Device Manufacturer: Dade Behring Inc.
Contact name: Maureen Mende, Group Manager Regulatory Affairs
Fax: 916-374-3144
Date prepared: January 15, 2002
Product Name: Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name: MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo panels
Intended Use: To determine antimicrobial agent susceptibility
510(k) Notification: Antimicrobials: Ofloxacin, Norfloxacin, Levofloxacin, Lomefloxacin, Sparfloxacin, and Ciprofloxacin
Predicate device: MicroScan Dried Gram Negative MIC/Combo Panels

510(k) Summary:

MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-negative bacilli. The MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo Panels are read on the WalkAway® SI System or equivalent (upgraded WalkAway® 40 or WalkAway® 96 instruments).

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in Mueller-Hinton Broth to concentrations bridging the range of clinical interest and are presented in micro-titer wells in dried form. The rapID/S *plus*™ panels are inoculated and rehydrated with a standardized suspension of the organism and incubated at 35°C in the WalkAway® SI System or equivalent for 4.5 – 18 hours. The minimum inhibitory concentration (MIC) for the test organism is determined by the lowest antimicrobial concentration showing inhibition of growth.

The proposed MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo Panel demonstrated substantially equivalent performance when compared with an NCCLS frozen Reference Panel, as defined in the FDA DRAFT document "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices", dated March 8, 2000. The Premarket Notification (510[k]) presents data in support of the MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo Panel with Ofloxacin, Norfloxacin, Levofloxacin, Lomefloxacin, Sparfloxacin, and Ciprofloxacin.

The external evaluation was conducted with fresh and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed rapID/S *plus*™ Gram-Negative Panel by comparing its performance with an NCCLS frozen Reference panel. Challenge strains were compared to Expected Results determined prior to the evaluation. The rapID/S *plus*™ Gram-Negative Panel demonstrated acceptable performance with an overall Essential Agreement of 98.3% for Ofloxacin, 97.4% for Norfloxacin, 98.2% for Levofloxacin, 98.6% for Lomefloxacin, 98.6% for Sparfloxacin and 98.3% for Ciprofloxacin when compared with the frozen Reference panel.

Instrument reproducibility testing demonstrated acceptable reproducibility and precision with Ofloxacin, Norfloxacin, Levofloxacin, Lomefloxacin, Sparfloxacin, and Ciprofloxacin with Turbidity inoculum preparation method and the WalkAway® SI System or equivalent (upgraded WalkAway® 40 or WalkAway® 96 instruments).

Quality Control testing demonstrated acceptable results for Ofloxacin, Norfloxacin, Levofloxacin, Lomefloxacin, Sparfloxacin, and Ciprofloxacin.

Section 1. LABELING SUMMARY

Labeling Changes Requiring FDA Clearance Prior to Implementation

- Clearance is requested for an MIC range which allows MicroScan the ability to select any number of antimicrobial for inclusion on future panels. The combination of dilutions chosen will be verified for acceptable performance, as defined in the DRAFT FDA guidance document titled "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices", dated March 8, 2000, prior to release. The dilutions requested, for use with gram-negative are indicated below:

Antimicrobial	Panel Type	Abbreviation	MIC Dilutions Requested
Ciprofloxacin	gram-negative	Cp	0.25 – 8 µg/ml
Levofloxacin	gram-negative	Lvx	0.5 – 16 µg/ml
Lomefloxacin	gram-negative	Lmf	1.0 – 16 µg/ml
Norfloxacin	gram-negative	Nxn	0.12 – 32 µg/ml
Ofloxacin	gram-negative	Ofx	0.12 – 16 µg/ml
Sparfloxacin	gram-negative	Sfx	0.5 – 8 µg/ml

- The following FDA Interpretive Breakpoints will be added to the MicroScan[®] rapID/S *plus*[™] Procedural Manuals:

Interpretive Breakpoints ¹			
Antimicrobial Agents	Susceptible	Intermediate	Resistant
Ciprofloxacin	≤1	2	≥4
Levofloxacin ²	≤2	4	≥8
Lomefloxacin ³	≤2	4	≥8
Norfloxacin ³	≤4	8	≥16
Ofloxacin ³	≤2	4	≥8
Sparfloxacin ⁴	≤1	2	≥4

1. Based on Interpretive Breakpoints as indicated in NCCLS Document M100-S11. There are antimicrobials included on the rapID/S *plus*[™] panels that are not proven to be effective for treating clinical infections for all organisms that may be tested. For interpreting and reporting of antimicrobial results which have shown to be active against organism groups, both *in-vitro* and in clinical infections, refer to NCCLS M100 Performance Standard Table1 or the pharmaceutical antibiotic labeling.

2. Interpretive criteria for urinary tract infections are only for *P.aeruginosa* and Other Non-Enterobacteriaceae,

3. Interpretive criteria applies to urinary tract infections only.

4. Interpretive criteria applies to Enterobacteriaceae only.

- The following Performance Characteristics claims will be added to the Procedural Manual:

Percent Agreement to Reference Method

Antimicrobial Agent	Essential Agreement (%)	Categorical Agreement (%)
Ciprofloxacin	640/651(98.3)	604/651 (92.8)
Levofloxacin	639/651 (98.2)	614/651 (94.3)
Lomefloxacin	642/651 (98.6)	618/651 (94.9)
Norfloxacin	634/651 (97.4)	609/651 (93.5)
Ofloxacin	640/651 (98.3)	609/651 (93.5)
Sparfloxacin	561/569 (98.6)	548/569 (96.3)

- The following QC ranges will be added to the Quality Control Manual:

Antimicrobial Agent	Abbreviation	<i>E. coli</i> ATCC 25922 Range ¹	<i>P. aeruginosa</i> ATCC 27853 Range ¹
Ciprofloxacin	Cp	<= 0.25	<= 0.25-1
Levofloxacin	Lvx	<= 0.5	<=0.5-4
Lomefloxacin	Lmf	<= 1.0	<=1-4
Norfloxacin	Nxn	<= 0.12	1-4
Ofloxacin	Ofl	<= 0.12	1-8 ²
Sparfloxacin	Sfx	<= 0.5	<=0.5-2 ³

1. Range = Expected value (µg/ml)

2. Out-of-range results may require extended incubation and reporting may range from 16-20 hours.

3. Organism intended for Quality Control Testing only.

- The following limitations will be added to the Limitations Section of the MicroScan[®] rapID/S *plus*[™] Gram-Negative Procedural Manual:
 - For Ofloxacin confirm and report *Pseudomonas aeruginosa* results at 16 – 20 hours incubation.

MicroScan rapidID/S *plus*™ Gram - Negative Procedural Manual



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 14 2004

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Robert Eusebio
Manager Regulatory Affairs
Dade MicroScan, Inc.
1584 Enterprise Boulevard
West Sacramento, CA 95691

Re: k020142
Trade/Device Name: MicroScan® Synergies Plus Gram Negative MIC/Combo Panels
with Ofloxacin, (0.12-16 µg/ml), Norfloxacin (0.12-32 µg/ml),
Levofloxacin (0.5-16 µg/ml), Lomefloxacin (1.0-16 µg/ml),
Sparfloxacin (0.5-8 µg/ml), Ciprofloxacin (0.25-8 µg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial
Susceptibility System
Regulatory Class: II
Product Code: LON
Dated: February 13, 2002
Received: February 15, 2002

Dear Mr. Eusebio:

This letter corrects our substantially equivalent letter of March 14, 2002, regarding the trade name which was changed to MicroScan® Synergies Plus to better reflect the intended use of the device.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-3084. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K020142

Device Name: MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panels with Ofloxacin (0.12 – 16 µg/ml), Norfloxacin (0.12 – 32 µg/ml), Levofloxacin (0.5 – 16 µg/ml), Lomefloxacin (1.0 – 16 µg/ml), Sparfloxacin (0.5 – 8 µg/ml), Ciprofloxacin (0.25 – 8 µg/ml)

Indications For Use:

MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic Gram-Negative bacilli (Enterobacteriaceae, glucose non-fermenters, and non-Enterobacteriaceae glucose fermenters. After inoculation, panels are read on the WalkAway® SI System or equivalent (upgraded WalkAway® 40 or WalkAway® 96) according to the Package Insert.

This particular submission is for the antimicrobials Ofloxacin, Norfloxacin, Levofloxacin, Lomefloxacin, Sparfloxacin, and Ciprofloxacin on the Synergies plus™ Gram-Negative MIC/Combo Panels.

The Gram-Negative organisms which may be used for Ofloxacin (Of), Norfloxacin (Nxn), Levofloxacin (Lvx), Lomefloxacin (Lmf), Sparfloxacin (Sfx), and Ciprofloxacin (Cp) susceptibility testing in this panel are listed in the attached table.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

INDICATIONS FOR USE STATEMENT

Page 2 of 3.

510(k) Number (if known): K_____

Device Name: MicroScan® rapID/S plus™ Gram-Negative MIC/Combo Panels with Ofloxacin, (0.12 – 16 µg/ml), Norfloxacin (0.12 – 32 µg/ml), Levofloxacin (0.5 – 16 µg/ml), Lomefloxacin (1.0-16 µg/ml), Sparfloxacin (0.5 – 8 µg/ml), Ciprofloxacin (0.25 – 8 µg/ml)

Indications For Use:

ORGANISMS INTENDED FOR TESTING

Organism	Cp	Lvx	Lmf	Nxn	Ofi	Sfx
<i>Acinetobacter baumannii</i>		X				X
<i>Acinetobacter calcoaceticus</i>		X		X	X	
<i>Acinetobacter lwoffii</i>	X	X				X
<i>Aeromonas caviae</i>	X				X	
<i>Aeromonas hydrophila</i>	X		X		X	
<i>Aeromonas</i> spp				X		
<i>Alcaligenes</i> spp				X		
<i>Citrobacter koseri</i> (diversus)	X	X		X	X	X
<i>Citrobacter freundii</i>	X	X	X	X	X	
<i>Edwardsiella tarda</i>	X			X		
<i>Escherichia coli</i>	X	X	X	X	X	
<i>Enterobacter aerogenes</i>		X	X	X	X	X
<i>Enterobacter agglomerans</i>		X	X			
<i>Enterobacter cloacae</i>	X	X	X	X	X	X
<i>Enterobacter sakazakii</i>		X				
<i>Flavobacterium</i> spp				X		
<i>Hafnia alvei</i>			X	X		
<i>Klebsiella oxytoca</i>	X	X	X	X	X	X
<i>Klebsiella ozaenae</i>			X			
<i>Klebsiella pneumoniae</i>	X	X	X	X	X	X
<i>Klebsiella rhinoscleromatis</i>				X		
<i>Morganella morganii</i>	X	X	X	X	X	X
<i>Pasteurella multocida</i>	X					
<i>Proteus mirabilis</i>	X	X	X	X	X	X
<i>Proteus vulgaris</i>	X	X	X	X	X	X

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR
(Optional Format 1-2-96)

Over-The-Counter Use _____

INDICATIONS FOR USE STATEMENT

Page 3 of 3.

510(k) Number (if known): K _____

Device Name: MicroScan® rapID/S plus™ Gram-Negative MIC/Combo Panels with Ofloxacin, (0.12 – 16 µg/ml), Norfloxacin (0.12 – 32 µg/ml), Levofloxacin (0.5 – 16 µg/ml), Lomefloxacin (1.0 – 16 µg/ml), Sparfloxacin (0.5 – 8 µg/ml), Ciprofloxacin (0.25 – 8 µg/ml)

Indications For Use:

ORGANISMS INTENDED FOR TESTING (cont.)

Organism	Cp	Lvx	Lmf	Nxn	Ofi	Sfx
<i>Providencia alcalifaciens</i>			X	X		
<i>Providencia rettgeri</i>	X	X	X	X	X	
<i>Providencia stuartii</i>	X	X		X	X	
<i>Pseudomonas aeruginosa</i>	X	X	X	X	X	
<i>Pseudomonas fluorescens</i>		X				
<i>Serratia liquefaciens</i>			X			
<i>Serratia marcescens</i>	X	X	X	X	X	
<i>Shigella boydii</i>	X					
<i>Shigella dysenteriae</i>	X					
<i>Shigella flexneri</i>	X					
<i>Shigella sonnei</i>	X					
<i>Shigella spp</i>				X		
<i>Salmonella enteritidis</i>	X					
<i>Salmonella spp</i>				X		
<i>Salmonella typhi</i>	X					
<i>Yersinia enterocolitica</i>	X			X		
<i>Vibrio cholerae</i>	X			X		
<i>Vibrio parahaemolyticus</i>	X			X	X	
<i>Vibrio vulnificus</i>	X					

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR
(Optional Format 1-2-96)

Over-The-Counter Use _____.